Electronic Certificate

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Country: Headquarter

Product: Avacopan

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Type: Cross-Functional Material

Subtype: Leave Piece

Classification:

Objective: Provide a handed pocket-guide to medical community members on the publication of updated EULAR guidelines for treating AAV.

Certification Statement

We certify that the final electronic form of this material is in accordance with the regulations set forth by the health authority for the country of this document, and is a fair and truthful presentation of the facts about the product.

Role	Signature
Achim Obergfell - Approval (aobergfell@viforpharma.com)	Meaning: As the Medical Signatory, I approve this document for use. Date: 17-Apr-2023 07:18:19 GMT+0000

EULAR recommendations for the management of AAV: 2022 update

REMISSION INDUCTION IN GPA/MPA[1]

Active GPA/MPA (new-onset OR relapsing)

No organ- or life-threatening manifestations

- Rituximab (1)
- OR
- (Methotrexate)
- OR
- (Mycophenolate mofetil)

Organ- or life-threatening disease

- Rituximab*
- OR
- Cyclophosphamide

RPGN (serum creatinine >300 µmol/L)

- (3) Consider plasma exchange

\+ GC OR (Avacopan)† (2)

(4) Taper GCs to 5 mg/day after 4–5 months → **Remission?‡**

GC start dose (mg/day) and stepwise tapering targets, depending on body weight[§]

Weight (kg)	W1¶	W2	W3 –4	W5 –6	W7 –8	W9 –10	W11 –12	W13 –14	W15 –18	W19 –52**
<50	50	25	20	15	12.5	10	7.5	6	5	5
50–75	60	30	25	20	15	12.5	10	7.5		
>75	75	40	30	25	20	15	12.5	10	7.5	

KEY CHANGES FOR 2022

1. Recommendation for **rituximab** use **irrespective of disease manifestations**
2. Option to use **avacopan** as part of a strategy **to reduce GC exposure**
3. Recommendation for use of **plasma exchange** limited to **RPGN**
4. Clear guidance on **GC start dose and tapering** provided

*Rituximab preferred in relapsing disease. †As part of a strategy to substantially reduce GC exposure. ‡ If remission not achieved, consult an expert centre; if remission achieved, proceed to maintenance phase. §For patients on rituximab or cyclophosphamide induction regimens; based on PEXIVAS scheme. ¶Use of intravenous methylprednisolone at a cumulative dose of 1–3 g on days 1–3 can be considered in patients with severely active disease; lowering the starting dose to 0.5 mg/kg/day can be considered in individual patients without organ-threatening or life-threatening manifestations. **Individual tapering recommended after 52 weeks.
GC doses are provided as prednisolone equivalent. Always refer to the product prescribing information for approved indications.
AAV, ANCA-associated vasculitis; ANCA, antineutrophil cytoplasmic antibody; EULAR, European League Against Rheumatism; GC, glucocorticoid; GPA, granulomatosis with polyangiitis; MPA, microscopic polyangiitis; RPGN, rapidly progressive glomerulonephritis.

1. Hellmich B et al. *Ann Rheum Dis* 2023. doi:10.1136/ard-2022-223764 (Epub ahead of print).

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EULAR recommendations for the management of AAV: 2022 update

REMISSION MAINTENANCE IN GPA/MPA[1]

1. Rituximab (preferred) **OR** (Azathioprine) **OR** (Methotrexate)

2. Continue therapy to maintain remission for 24–48 months

Continue GC taper / Stop avacopan*

If relapse → Treat as for **remission induction**

If sustained remission and GCs/avacopan stopped → 3. Assess individual relapse risk, comorbidities and patient preferences → 4. Continue† or stop treatment

KEY CHANGES FOR 2022

1. Rituximab recommended as preferred immunosuppressant
2. Recommended duration of maintenance therapy extended
3. Need for individualised treatment emphasised
4. Advice on treatment cessation added

PROPHYLAXIS AND MONITORING[1]

In patients using rituximab, cyclophosphamide and/or high-dose GCs, trimethoprim-sulfamethoxazole recommended as **prophylaxis against *pneumocystis jirovecii* pneumonia and other infections**

Check for **secondary immunodeficiency** in patients receiving rituximab by measuring serum Ig concentrations prior to initiation of each treatment course

Base decisions to change treatment strategy on **clinical assessment** (not on ANCA and/or CD19+ B cell testing alone)

OVERARCHING PRINCIPLES: Patients with GPA/MPA should receive…

Best care, based on **patient–physician shared decision-making**, considering efficacy, safety and costs

Access to education, focussing on disease impact and prognosis, key warning symptoms and treatment (including related complications)

Periodical screening for treatment-related AEs and comorbidities, with **prophylaxis** and **lifestyle advice** to reduce these

Multidisciplinary management from centres with/with ready access to specific vasculitis expertise

*Stop avacopan after 6–12 months; there are no data on use of avacopan beyond 1 year, so longer-term use cannot be recommended. †Longer duration of treatment should be balanced against patient preferences and risks of continuing immunosuppression. Always refer to the product summary of product characteristics for approved indications before prescribing.
AAV, ANCA-associated vasculitis; AE, adverse event; ANCA, antineutrophil cytoplasmic antibody; EULAR, European League Against Rheumatism; GC, glucocorticoid; GPA, granulomatosis with polyangiitis; Ig, immunoglobulin; MPA, microscopic polyangiitis.

1. Hellmich B et al. *Ann Rheum Dis* 2023. doi:10.1136/ard-2022-223764 (Epub ahead of print).

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